UNITED STATES DEPARTMENT OF COMMERCE
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Washington, D.C. 20231

JUL 29 1999

David T. Read
Acting Director Regulatory Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

Dear Mr. Read:

The attached application for patent term extension of U.S. Patent No. 5,362,755 was filed on May 21, 1999, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, XOPONEX® (levalbuterol hydrochloride), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156 IF the approval of XOPONEX® (levalbuterol hydrochloride) is considered the first permitted use of levalbuterol hydrochloride, or a salt or ester thereof. As noted in the application, albuterol has been previously approved and albuterol contains levalbuterol hydrochloride. See also the Prescription Drug Product List, Page 3-10, Approved Drug Products with Therapeutic Equivalence Evaluations, 18th Edition, attached. In addition, the posting on FDA's home page (http://www.fda.gov/cder/da/da0399.HTM) for the approval of XOPONEX indicates that the approval of levalbuterol hydrochloride the approval of a new formulation (a new dosageform or new formulation of an active ingredient already on the market) and not a new drug. See attachment 2.

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)308-6916 (facsimile).

Karin Tyson
Senior Legal Advisor/Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: HAROLD C. WEGNER
FOLEY & LARDNER
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WASHINGTON DC 20007-5109

Attachment #1

ALBENDAZOLE

TABLET; ORAL
ALBENZA
+ SMITHKLINE BEECHAM 200MG N20666 001 JUN 11, 1996

ALBUMIN CHROMATED CR-51 SERUM

INJECTABLE; INJECTION
CHROMALBIN
ISO TEX 100 uCi/VIAL N17835 001

ALBUMIN HUMAN

INJECTABLE; INJECTION
OPTISON
+ MOLECULAR BIOSYSTEMS 10MG/ML N20899 001 DEC 31, 1997

ALBUMIN IODINATED I-125 SERUM

INJECTABLE; INJECTION
RADIOIODINATED SERUM ALBUMIN (HUMAN) IHSA I 125
MALLINCKRODT 6.67 uCi/ML N17844 003
10 uCi/ML N17844 001
100 uCi/ML N17844 002

ALBUMIN IODINATED I-131 SERUM

INJECTABLE; INJECTION
MEGATOPE
ISO TEX 0.5mCi/VIAL N17837 001
1mCi/VIAL N17837 002

ALBUTEROL

AEROSOL, METERED; INHALATION
ALBUTEROL
AB ALPHARMA 0.09MG/INH N73045 001 AUG 19, 1997
AB MEDEVA 0.09MG/INH N72273 001 AUG 14, 1996

ALBUTEROL

AEROSOL, METERED; INHALATION
ALBUTEROL
AB MEDISOL 0.09MG/INH N74072 001 AUG 01, 1996
AB NORTON WATERFORD 0.09MG/INH N73272 001 DEC 28, 1995
PROVENTIL
BN SCHERING 0.09MG/INH N17559 001
VENTOLIN
AB + GLAXO WELLCOME 0.09MG/INH N18473 001

ALBUTEROL SULFATE

AEROSOL, METERED; INHALATION
PROVENTIL-HFA
+ 3M EQ 0.09MG BASE/INH N20503 001 AUG 15, 1996

CAPSULE; INHALATION
VENTOLIN ROTACAPS
+ GLAXO WELLCOME EQ 0.2MG BASE N19489 001 MAY 04, 1988

SOLUTION; INHALATION
ALBUTEROL SULFATE
AN ALPHARMA EQ 0.083% BASE N73533 001 SEP 26, 1995
AN COPLEY PHARM EQ 0.083% BASE N73495 001 MAY 28, 1993
AN EQ 0.5% BASE N73307 001 NOV 27, 1991
AN DEY EQ 0.083% BASE N72652 001 FEB 21, 1992
AN NEPHRON EQ 0.083% BASE N74880 001 SEP 17, 1997
PROVENTIL
AN + SCHERING EQ 0.083% BASE N19243 002 JAN 14, 1987
AN + EQ 0.5% BASE N19243 001 JAN 14, 1987
VENTOLIN
AN + GLAXO WELLCOME EQ 0.083% BASE N19773 001 APR 23, 1992
AN + EQ 0.5% BASE N19269 002 JAN 16, 1987

Attachment # 2

U.S. Food and Drug Administration
Center for Drug Evaluation and Research

Drug Approvals for March 1999

Definitions and Notes

March 1999

Original New Drug Applications

Original Application #: 020966
Approval Date: 30-MAR-99
Trade Name: SPORANOX
Chemical Type: 3
Therapeutic Potential: S
Dosage Form: INJECTABLE
Applicant: JANSSEN RESEARCH FDN DIV JOHNSON AND JOHNSON
Active Ingredient(s): ITRACONAZOLE
OTC/RX Status: RX
Indication(s): For the treatment of blastomycosis, histoplasmosis and aspergillosis in immunocompromised and non-immunocompromised patients

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Original Application #: 020908
Approval Date: 26-MAR-99
Trade Name: VAGIFEM
Chemical Type: 3
Therapeutic Potential: S
Dosage Form: TABLET
Applicant: NOVO NORDISK PHARMACEUTICAL INC
Active Ingredient(s): ESTRADIOL
OTC/RX Status: RX
Indication(s): For the relief of postmenopausal atrophic vaginitis due to estrogen deficiency

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Original Application #: 020837
Approval Date: 25-MAR-99
Trade Name: XOPENEX
Chemical Type: 3
Therapeutic Potential: S
Dosage Form: SOLUTION
Applicant: SEPRACOR PHARMACEUTICALS
Active Ingredient(s): LEVALBUTEROL HYDROCHLORIDE

OTC/RX Status: RX
Indication(s): For the treatment or prevention of bronchospasm in adults and adolescents 12 years of age and older with reversible obstructive airway disease

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Original Application #: 020992
Approval Date: 24-MAR-99
Trade Name: CENESTIN
Chemical Type: 3
Therapeutic Potential: S
Dosage Form: TABLET
Applicant: DURAMED PHARMACEUTICALS INC
Active Ingredient(s): ESTROGENS, CONJUGATED
OTC/RX Status: RX
Indication(s): For use in the treatment of moderate-to-severe vasomotor symptoms associated with the menopause

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Original Application #: 020612
Approval Date: 19-MAR-99
Trade Name: LIDODERM
Chemical Type: 3
Therapeutic Potential: S
Dosage Form: FILM, EXTENDED RELEASE
Applicant: HIND HEALTH CARE
Active Ingredient(s): LIDOCAINE
OTC/RX Status: RX
Indication(s): For the treatment of pain in post-herpatic neuralgia

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Original Application #: 020980
Approval Date: 09-MAR-99
Trade Name: LAMISIL
Chemical Type: 6
Therapeutic Potential: S
Dosage Form: EMULSION, CREAM
Applicant: NOVARTIS PHARMACEUTICALS CORP
Active Ingredient(s): TERBINAFINE HYDROCHLORIDE
OTC/RX Status: OTC
Indication(s): For the treatment of tinea pedis (athlete's foot), tinea cruris (jock itch) and tinea corporis (ringworm) due to Epidermophyton floccosum, Trichophyton mentagrophytes and Trichophyton rubrum

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Original Application #: 020994